AN ARTIFICIAL HEART WITH THE RIGHT CONNECTION

Alex Robinson

Abstract • Résumé

Led by Dr. Tofy Mussivand at the University of Ottawa Heart Institute, a team of Canadian medical scientists, engineers, economists, physicians and medical devices manufacturers is working to bring a prototype artificial heart closer to clinical trials. Key to this effort is the development of an electrical connector that can function for a long period in the harsh environment of the human body. Such a connector will enable various components of the artificial heart, such as the internal battery, to be replaced independently. As well as being of obvious benefit to people with end-stage heart disease, a Canadian-made artificial heart has export potential that should help to redress the country's large trade deficit in medical devices.

Dirigée par le Dr Tofy Mussivand de l'Institut de cardiologie de l'Université d'Ottawa, une équipe canadienne de chercheurs médicaux, d'économistes, d'ingénieurs, de médecins et de fabricants d'instruments médicaux cherche à rapprocher davantage du stade des études cliniques un prototype de coeur artificiel. Cet effort pivote sur la mise au point d'un connecteur électrique pouvant fonctionner pendant longtemps dans l'environnement rigoureux qu'est le corps humain. Ce connecteur permettra de remplacer indépendamment les divers composants du coeur artificiel, la pile interne par exemple. Sans compter l'avantage évident pour les gens qui souffrent de cardiopathies terminales, un coeur artificiel fabriqué au Canada offre un potentiel d'exportation qui devrait aider à réduire l'important déficit commercial du Canada dans le secteur des instruments médicaux.

A grant to support the development of a specialized electrical connector is helping to keep alive the dream of a made-in-Canada artificial heart that can deliver an acceptable quality of life at a reasonable price. Sound like a tall order? Not when Dr. Tofy Mussivand describes how the components of the artificial heart, connector included, fit together.

A professor in the University of Ottawa's Faculty of Medicine and director of the Cardiovascular Devices Division of the University of Ottawa Heart Institute, Mussivand leads the Canadian Artificial Heart Program, which was set up by Dr. Wilbert Keon in 1989 to develop an implantable electrohydraulic ventricular assist device — an EVAD.[1-4]

Since then Mussivand's team has grown to 165 collaborators — including volunteer scientists from across Canada — and the program has received more than $11 million in grants from Canada and other nations. Adding the value of voluntary work done by scientists and engineers, Mussivand guesses that the program has drawn the equivalent of $20 to $25 million. But recent provincial funding cuts have left him plainly worried about the program's future. So a 3-year grant worth $125 000 that is to be shared with an Ottawa firm offers some hope. From the University Research Incentive Fund of the Ontario Ministry of Education and Training, the grant is for the design of a connector able to withstand the harsh environment inside the human body.

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THE PROBLEM

To put the work on the connector in context, Mussivand steps back to look at the problem an artificial heart is intended to solve. "In North America and Europe about half of all deaths are due to cardiovascular disease," he notes. "Every year 44 000 Canadians die of heart failure and 500 000 die of it in the United States." More than 4 in 10 of those who die are younger than 65 years of age.

To reduce the risk of death due to heart disease physicians talk about prevention and turn to various treatments. But it takes several generations for health-related habits to change, says Mussivand, and most of today's treatments have limitations. Perhaps the best answer, heart transplantation, runs into a stone wall: fewer than 3000 donor hearts become available every year.

Mussivand pondered these numbers, the conventional answers, and some decidedly unconventional ones when

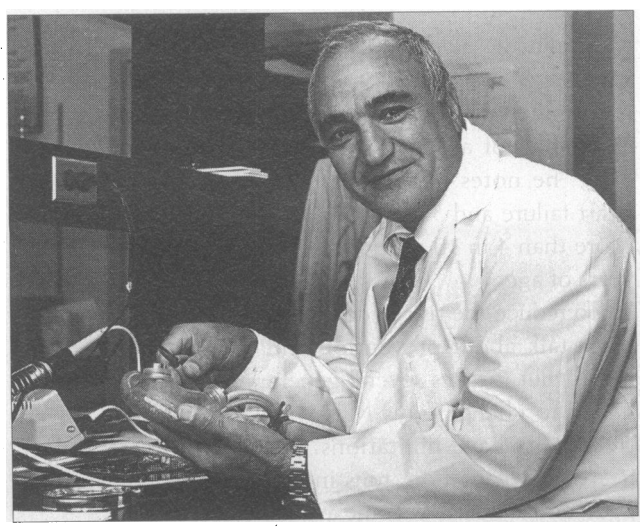
he was asked to lead the Canadian Artifical Heart Program. He thought about how it could reach the goal of developing an EVAD, about the difficulties of designing a device that would be convenient to use and relatively inexpensive and about the artificial hearts then being developed. His observations left him with a single question: Why aren't artificial hearts viable?

There are six main obstacles, Mussivand concluded. The first is size and weight — in other words, anatomic compatibility. The second is power: "You need 5 to 30 watts of power, and that's a lot. Until recently patients were tethered to consoles, bedridden because of the power supply." The third is monitoring and control of the artificial heart, which "used to be done invasively, with cables and hoses passing through the patient's skin and tissue barriers." Fourth is the need to prevent blood from clotting as it passes through such devices. Fifth is quality of life — or lack thereof if a patient is attached to heavy external machinery. The sixth is affordability: "If the artificial heart is too expensive, it is not helpful."

Mussivand's solution

Mussivand assembled his team with the objective of creating a device that satisfied the program's goals by offering left ventricular support. The prototype was ready in 1993 and is now being tested.

The internal parts of the EVAD include an electrohydraulic pump connected to the patient's natural heart and circulatory system and an implanted battery linked to the pump by the connector now being developed. Power and data are transferred to and from the pump in the form of magnetic waves through intact skin. This is achieved by means of two small pancake-shaped coils — one implanted under the skin and connected to the pump, and one resting on the outside of the body over the implanted coil. An external battery powers the external controller, which drives the power and data transfers. Both the external battery and the controller are worn on a belt to afford the patient total mobility.



Dr. Tofy Mussivand holding a prototype of the electrohydraulic ventricular assist device.

"Canadians will be using artificial hearts within a decade."

— Dr. Tofy Mussivand

The EVAD is designed to be a very simple mechanism, says Mussivand. "The more complex the design, the higher the risk that it will not be reliable." It has three control modes: the manual mode allows the clinician to control the pumping rate, the default mode maintains a fixed pumping rate, and the variable mode permits the pumping rate to change according to the patient's physiologic needs. "In the variable mode the artificial heart increases its pumping rate when blood flow to it increases. When the flow decreases, the pumping rate decreases."

The thin, oval pump is compact enough to fit in Mussivand's hand. More important, it will be a good fit in the chests of patients.[5] "We have addressed the question of fit," he says, "and we now have an answer for the second block, the problem of power."

The answer is newly patented technology by which electrical power for the pump can be sent from the lead of the external controller into the electronics inside the pump. "This technology eliminates the need for cables that perforate the protective skin and tissue."

The technology also permits the passage of control and monitoring signals. Signals pass through the skin as light waves between the pump and the external controller, which could have a built-in modem so that "control and monitoring can be done wherever there is a telephone. Six months ago we demonstrated this concept between Ottawa and Geneva."

To make such a connection work, the patient would connect the external controller to a telephone line, and the physician or clinical engineer at the other end would feed the signal into a computer. A computer program would assess how the heart was working and then, if necessary, send information to the heart to change its operation. "Telemedicine in action," says Mussivand.

So far, problems with blood clotting have not been encountered. But Mussivand admits that there have been few opportunities to test for these so far. He is more optimistic about the improvement in quality of life that the device will deliver. "We expect a drastic improvement. It can be put in the patient's chest. Patients will leave the

hospital mobile, able to take care of themselves and to resume normal activities. And the device will be permanent in some patients who require no other treatment."

The device can be powered three ways: the external controller can accept electrical power from a wall socket, the external battery can hold a charge of perhaps 6 to 8 hours, and the internal battery can hold about a 45-minute charge.

Finally, Mussivand turns to the matter of cost: "It's a competitive technology," he says, "with a much lower cost than some alternative products." This is where the connector fits in.

The connector

It is to be expected, Mussivand explains, that some of the internal elements of the artificial heart will wear down over time. The internal battery, for example, may need to be replaced.

It doesn't make sense to remove all the internal parts of an artificial heart just to replace a battery. Hence the need for a connector that can function for long periods inside the body. "With a connector in place, only the battery would need to be removed — a much smaller, safer, less painful and less expensive procedure." Modified versions of the connector could link all the internal subsystems of the artificial heart.

Work to date has yielded a good candidate with a bayonet-style, cylindrical, pin-and-socket design. The candidate connector uses materials with established biocompatibility records. Preliminary testing suggests satisfactory performance.[6] The goal of design work is now to reduce the connector's size. Further experiments will show whether it should be brought forward to clinical testing.

Next steps

Mussivand says that over $300 million has been spent in the United States on research into artificial hearts. With a twelfth of these resources he believes he is 2 to 4 years from human clinical trials with the EVAD. After clinical trials will be the hurdle of obtaining marketing approval for the product from the Canadian Bureau of Medical Devices and the US Food and Drug Administration.

The prospect of a lost global market for a high-tech product is, in part, what fuels Mussivand's frustration at recent provincial research funding cuts that affect his program. "Canadians will be using artificial hearts within a decade," he says. "If the artificial hearts are not made in Canada we will have to buy them in the country where they are made, adding to our already large medical devices trade deficit." He continues, "It will cost $50 million to $100 million a year to bring this technology in — and it will be brought in, since no one can stop people from using life-saving technologies."

Meanwhile, more than 20 customers from other nations have bought or are negotiating to buy components developed by the Canadian team for the EVAD. Exports have generated more than $150 000, he says, and the market potential for spin-off technologies is projected at $150 million a year.

On a table in his lab, an early prototype of Mussivand's EVAD has been beating for more than 3 years. Not surprisingly, it doesn't sound like a heart — it has the measured wheeze of a mechanical pump. Perhaps it wouldn't sound that way to someone whose life depended on it. In any case, more recent models are so quiet that a patient fitted with an EVAD might not even hear it working.

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